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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,447	09/01/1999	Sachdev S. Sidhu	P1581R2	2633
23552	7590	10/03/2003	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			TRAN, MY CHAU T	
			ART UNIT	PAPER NUMBER
			1639	23
DATE MAILED: 10/03/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,447

Applicant(s)

SIDHU ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10 and 13-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,11 and 12 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1-4, 7-9, and 11-12) in Paper No. 19 is acknowledged. The traversal is on the ground(s) that "[t]he examiner did not follow Rule 13.1 and Rule 13.2 in determining Unity of invention for a national stage application". This is not found persuasive because the examiner has shown that there is a lack of unity of the claimed invention in accord with Rule 13.1 and Rule 13.2. The claimed invention is a fusion protein that is fused to a major coat protein of a virus regardless of its variant. However, Scott et al. (1990) disclose the bacteriophage display technique by which polypeptides are displayed as fusion proteins to the coat protein on the surface of bacteriophage particles (Abstract; pg. 386, right col., lines 15-27). Therefore the claimed invention (Groups I-XII) are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 5-6, 10, 13-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 19.

3. Applicant's election of species in Paper No. 19 is acknowledged. The elected species are as follows: a) major coat protein gp VIII of a phage; b) a variant of a wild type major coat protein with a substitution at amino acid position 17 of a serine with an isoleucine; c) an antibody or fragment thereof as the heterologous protein.

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However, a letter of non-responsive mailed on 6/20/03 with regard to an incomplete species election to the requirement in the previous Office Action mailed 3/07/03. Applicant traverse this letter of non-responsive and provided the amino acid at each positions. Applicant elected the following amino acid for each position:

Position No./Amino Acid: 1/D, 2/K, 3/S, 4/E, 5/K, 6/F, 7/S, 8/R, 9/D, 11/Y, 12/E, 13/A,

Position No./Amino Acid: 14/L, 15/E, 16/D, 17/I, 18/I, 19/T, 20/N, 21/L, 22/F, 23/F,

Position No./Amino Acid: 24/L, 25/L, 26/G, 27/T, 28/V, 29/Y, 30/V.

The traversal is on the ground(s) that applicant did comply with the election of species requirement in the Office action mailed 3/07/03 wherein the species are as follows: a) A *single* type of virus (phage); b) A *single* type of coat protein; c) A *single* amino acid residue and its corresponding position (residue number). Applicant are further requested to recite the selected coat protein amino acid sequence which read on the elected amino acid residue at the different positions; c) A *single* type of heterologous polypeptide.

This is not found persuasive because applicant did not provide in Paper No. 19 a coat protein amino acid sequence that read on the elected amino acid residue at the different position. However since applicant provided the amino acid for each position in Paper No. 22 the argument is considered moot.

4. Claims 1-4, 7-9, and 11-12 are treated on the merit in this Office Action.

Claim Objections

5. Claim 11 is objected to as an improper dependent claim since it depends on non-elected claim 20 that result in a broken pendency chain. However in order to further prosecution, Claim 11 is interpreted to depend on claim 9. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 7-9, and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

These claims encompass a broad genus of fusion protein that are fused to a major coat protein of a virus. For example, claim 1 briefly recites a fusion protein comprising a heterologous polypeptide fused to a major coat protein of a virus. The scope of this claim includes an infinite number of a heterologous polypeptide fused to a major coat protein wherein no distinguishing structural attributes are provided for the sequence of either the "heterologous polypeptide" or the "major coat protein". The specification and claims do not place any limit on the number of atoms, the types of atoms, or the manner in which said atoms might be connected to form the sequence of either the "heterologous polypeptide" or the "major coat protein".

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Although the specification discloses many possible sequences that "might" be the "major coat protein" (see Specification, pages 41-42) and "heterologous polypeptide" (see sequence listing), the specification and claims do not provide any guidance as to what structural features all of these heterologous polypeptide shares or these major coat protein shares. Consequently, it is not possible to determine *a priori* which sequences that the "heterologous polypeptide" and the "major coat protein" would encompass because there is no common structural attributes that can link together all of these potential sequences in either heterologous polypeptide and major coat protein i.e., there is no teaching that would allow a person of skill in the art to determine *a priori* all the different types of sequences that should be included in this genus from the few examples provide by applicants. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams,

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formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify all of the members of the genus or even a substantial portion thereof, and because the genus is enormous and highly variant, listing examples like coat proteins such as M13, fl, fd, and Zj-2 that are known in the literature (see specification, pages 39-40) is insufficient to teach the entire genus. Consequently, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe this enormous genus. Thus, applicant was not in possession of the claimed genus.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The amino acid residue of position 10 is missing. Thus this sequence of the major coat protein is incomplete.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-2, 8-9, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (*Science*, 1990, 249(4967):386-390).

Scott et al. disclose a fusion protein that fused to the major coat protein of a filamentous phage (Abstract; pg. 386, left col., lines 1-4; pg. 386, right col., line 33 to pg. 387, left col. 1-19). The fusion protein is display on the surface of the phage (pg. 386, right col., lines 15-19). The expression vector of the host cell encodes the fusion protein (right col., line 33 to pg. 387, left col. 1-19). Thus the fusion protein of Scott et al. anticipates the presently claimed fusion protein.

12. Claims 1-3, 7, 9, and 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Light, II et al. (US Patent 5,770,356).

Light, II et al. disclose a filamentous phage comprise of a heterologous polypeptide fused to a coat protein membrane (Abstract; col. 9, lines 3-5 and lines 32-35). The heterologous polypeptide is display on the surface of the phage (col. 9, lines 32-35). The coated protein comprise of gpVIII (col. 10, lines 23-25). The expression vector of the host cell encodes the fusion protein (col. 22, lines 50-58). Thus the fusion protein of Light, II et al. anticipates the presently claimed fusion protein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999.

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The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30;
Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
September 30, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER